1644

Practitioner's Docket No. 20663/09003 *PATENT*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Minter H. Dopson

Application No.: 09/954,961 Group No.: 1644
Filed: 09/18/01 Examiner: Ronald B. Schwadron
For: TRANSFER FACTOR COMPOSITION AND PROCESS FOR PRODUCING SAME

Mail Stop Non-Fee Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)

I hereby certify that the attached correspondence comprising:

1. Response and Preliminary Amendment Transmittal (1 page);
2. Response to Restriction Requirement and Preliminary Amendment (6 pages);
3. Request to Provoke Patent Interference; (11 pages);
4. Revocation of Prior Powers of Attorney and New Power of Attorney (2 pages);
5. Statement Under 37 C.F.R. § 3.73(b) – Establishing Right of Assignee to Take Action w/copy of recorded Assignment (12 pages); and
6. Return Postcard.

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Deborah Anne Weiner

Deborah Anne Weiner

Signature of person mailing paper

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dopson	)	Group Art Unit: 1644
Serial No.: 09/954,961	)	Examiner: Ronald D. Schwadron
Filed: September 18, 2001	)	Deposit Account: 50-2548
Title: Transfer Factor Composition and Process for Producing Same	)	Docket No.: 20663/09003

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

REQUEST TO PROVOKE INTERFERENCE UNDER 37 C.F.R §1.607

Dear Sir:

Applicants hereby request to provoke an interference proceeding under 37 C.F.R. §1.607 with U.S. Patent No. 6,468,534 to Hennen, *et al.* (Hennen), which issued on October 22, 2002. The present application, Serial No. 09/954,961 (Dopson) has an effective filing date of September 18, 2000 while the Hennen patent has an effective filing date of September 21, 2000. Therefore, it is respectfully submitted that the Dopson application would be the senior party in any subsequent interference proceeding with the Hennen patent.

If any further extension of time or additional fees for the accompanying request are required, Applicant requests that this be considered a petition therefor. The Commissioner is hereby authorized to charge any additional fees, which may be required to Deposit Account 50-2548.

I. Identification of Patent with which Applicants Request to Provoke an Inteference

Applicants hereby identify U.S. Patent No. 6,468,534 to Hennen, *et al.* as claiming the same patentable invention as the present application, U.S. Serial No. 09/954,961 to Dopson.

II. Proposed Count

A method for obtaining transfer factor, comprising:

exposing a non-mammalian source animal to at least one antigenic agent that will cause said non-mammalian source animal to elicit a T-cell mediated immune response;

permitting said non-mammalian source animal to elicit a T-cell mediated immune response to said at least one antigenic agent;

collecting at least one egg from said non-mammalian source animal following said T-cell mediated immune response, said at least one egg including transfer factor that transfer cellular immunity to a mammal in vivo and that includes transfer factor molecules having molecular weights of about 4,000 Da to about 5,000 Da.

III. Hennen Claims That Correspond to the Proposed Count

Hennen issued with Claims 1-30. Applicants hereby identify Claims 1 – 30 of Hennen as corresponding to the above-proposed count. Claim 1 of Hennen is identical to the proposed count and the other claims of Hennen are directed to the same patentable invention.

IV. Hennen Claims 1-30 Correspond to the Proposed Count

Hennen Claims 1-30 correspond to the proposed count because Claim 1 is identical to the count and Claims 2-30 are obvious variants of the count.

V. Dopson Claims That Correspond to the Proposed Count

As a result of a preliminary amendment being filed herewith, the present application to Dopson contains Claims 1-9 and Claims 21 and 22. Applicants hereby identify currently pending Claims 1-9, Claims 21, and 22 of Dopson as corresponding to the proposed count.

VI. Dopson Claims 1-9 Correspond to the Proposed Count

Applicants submit that each limitation of Dopson's Claim's 1-9 correspond to the proposed count, including, but not limited to, the reasons stated below.

a) Limitation #1 of Dopson Claim 1: "A process for producing transfer factor, said process comprising the steps of"

The Claim 1 limitation of "A process for producing transfer factor, said process comprising the steps of" conveys the same meaning as the proposed count language of "A method for obtaining transfer factor, comprising".

b) Limitation #2 of Dopson Claim 1: "immunizing a female bird"

The Claim 1 limitation of "immunizing a female bird" corresponds substantially to the proposed count language of "exposing a non-mammalian source animal" because a "bird" is a species or subgenus of a generic "non-mammalian source animal". It is a general principle that the disclosure of a species or subgenus is sufficient to support a corresponding claim for the purpose of contesting priority on a count of relatively generic scope. See Den Beste v. Martin, 116 USPQ 584 (C.C.P.A. 1958).

c) Limitation #3 of Dopson Claim 1: "with a sufficient quantity of at least one selected antigen"

The Claim 1 limitation of "with a sufficient quantity of at least one selected antigen" is the same as the proposed count language of "to at least one antigenic agent". Both phrases substantially correspond to the addition of (*i.e.* immunization with) an antigen or antigenic agent.

d) Limitation #4 of Dopson Claim 1: "so that said bird develops immunity to said at least one antigen;"

The Claim 1 limitation of "so that said bird develops immunity to said at least one antigen;" substantially corresponds to the proposed count language of "that will cause said non-mammalian source animal to elicit a T-cell mediated immune response;"

The Claim 1 limitation of "develops immunity" to an antigen would be understood by one of skill in the art as inherently the same as eliciting a "T-cell mediated immune response". Many scientific publications, treatises and patents support the idea that

developing immunity to an antigen will necessarily involve a T-cell mediated immune response.

For example, the Hennen patent itself teaches in col. 2, lines 4-6 that "T-cells are primarily responsible for the secondary, or delayed-type hypersensitivity, immune response to a pathogen or antigenic agent." Likewise, Fundenberg, H., *et al.*, *Annual Review of Pharmacology and Toxicology*, Vol. 29, p. 5 (1989), supports the idea that developing immunity to an antigen is a T-cell mediated immune response by stating, "[w]e now reserve the term TF (*i.e.* transfer factor) for the components of DLE that transfers T-lymphocyte responses in an antigen-specific fashion. . . ." (*emphasis added*) Also, Rudin, N., Dictionary of Modern Biology, Barron's Educational Services, p. 363 (1997) describes T-cells as essential participants in the cell-mediated immune response.

In addition, the Dopson application describes in Example 1 a delayed-type hypersensitivity assay for testing chickens to determine if they had developed immunity after injection of an antigen. One of skill in the art will understand that the disclosure of a delayed-type hypersensitivity assay would inherently support a disclosure of a T-cell mediated immune response because such an assay is known to be a measure of a T-cell response. See *e.g.*, U.S. Patent to Hennen, *et al.* at col. 2, lines 4-6; U.S. Patent No. 6,576,428 to Assenmacher, *et al.*, at col. 4, lines 66-67, "T cells play important roles in autoimmunity, inflammation, cytotoxicity, graft rejection, allergy, *delayed-type hypersensitivity,* IgE-mediated hypersensitivity, and modulation of the humoral response" (*emphasis added*); and Lodish, H., *et al.*, *Molecular Cell Biology*, 3rd Edition, Scientific American Books, Inc., Chap. 27, p. 1331 (1997) (certain mobilization of

phagocytes by T_H-cells are called delayed-type hypersensitivity responses because they can take hours or days to develop).

e) Limitation #5 of Dopson Claim 1: "after said bird develops immunity to said at least one antigen,"

The Claim 1 limitation of "after said bird develops immunity to said at least one antigen," corresponds to the proposed count language of "permitting said non-mammalian source animal to elicit a T-cell mediated immune response to said at least one antigenic agent;". The "bird" limitation in Dopson's Claim 1 corresponds to the "non-mammalian source animal" in the proposed count essentially for the same reasons recited above, with respect to limitation #2 of Dopson's Claim 1. Likewise, the "immunity" limitation in Dopson's Claim 1 corresponds to the "T-cell mediated immune response" in the proposed count for the same reasons recited above with respect to limitation #4.

f) Limitation #6 of Dopson Claim 1: "collecting eggs laid by said bird;"

The Claim 1 limitation of "collecting eggs laid by said bird;" corresponds substantially to the proposed count language of "collecting at least one egg from said non-mammalian source animal following said T-cell mediated immune response,", for the same reasons described in limitations #2 and #4 above.

g) Limitation #7 of Dopson Claim 1: "and treating said eggs to recover transfer factor therefrom."

The Claim 1 limitation of "and treating said eggs to recover transfer factor therefrom" corresponds substantially to the proposed count language of "said at least one egg including transfer factor that transfer cellular immunity to a mammal in vivo and that includes transfer factor molecules having molecular weights of about 4,000 Da to about 5,000 Da." The transfer factor recovered from eggs in Dopson's Claim 1 is disclosed in the Dopson specification as being capable of transferring cellular immunity to a mammal *in vivo* as required by the proposed count. See Dopson, U.S. Serial No. 09/954,961, p. 2, lines 4-13 and p. 9, lines 4-9.

Finally, Applicant's specification discloses that transfer factors generally have molecular weights that range from approximately 3,000 – 6,000 Da. See Dopson, U.S. Serial No. 09/954,961, p. 2, lines 25-26. Thus, Applicant's range fully supports and encompasses the about 4,000 to about 5,000 Da range of the proposed count.

Applicant's Claims 2 - 9 also correspond to the proposed count as obvious variants the count.

In light of the foregoing arguments in limitations #1 through #7 of Claim 1, Applicants submit that each limitation of Dopson's Claim 1 - 9 substantially corresponds to the proposed count.

VII. Dopson Claims 21 and 22 Correspond to the Proposed Count

As an alternative to Requesting the Declaration of Interference based on Applicant's Claim's 1 – 9, new Claims 21 and 22 are being introduced into the present Dopson application by way of a preliminary amendment, which is filed simultaneously

herewith. Both new claims 21 and 22 are copied identically from the Hennen patent's Claim's 1 and 24.

a) New Claim 21 is fully supported by the Dopson disclosure and corresponds identically to the proposed count

Applicant's disclosure of a "bird" supports the limitation of "non-mammalian source animal" because, as stated previously, it is a general principle that the disclosure of a species or subgenus is sufficient to support a corresponding claim for the purpose of contesting priority on a count of relatively generic scope. See Den Beste v. Martin, 116 USPQ 584 (C.C.P.A. 1958). In addition, Dopson supports the "non-mammalian" limitation by the disclosure in p. 6, lines 10-12, that "there is a continuing need for a reliable, costeffective process that *does not* depend on cell culture or on the availability of cows, goats, *or other large mammals*." (*emphasis added*) Likewise, Dopson teaches in p. 7, lines 1-2 "an important feature of the present invention is the use of bird eggs *rather than mammalian tissue* (lymphocytes, milk, colostrum, etc.) as the starting material." (*emphasis added*)

Dopson's disclosure also supports the limitation of "elicit a T-cell mediated immune response" because the term of art, as discussed above, "develops immunity" is used at several instances throughout the application. See *e.g.*, Dopson, U.S. Serial No. 09/954,961, p. 7, lines 15-18.

The disclosure of "develops immunity" to an antigen would be understood by one of skill in the art as inherently supporting a claim limitation to "elicit a T-cell mediated immune response". Again, as discussed above, several scientific publications, treatises

and patents were cited above to support the proposition that developing immunity to an antigen will necessarily involve a T-cell mediated immune response.

In addition, Example 1 of Dopson (p. 16) describes a delayed-type hypersensitivity assay for testing female chickens to determine if they had developed immunity after injection of an antigen. As stated above, one of skill in the art will understand that the disclosure of a delayed-type hypersensitivity assay would inherently support a disclosure of a T-cell mediated immune response because such an assay is known to be a measure of a T-cell mediated response.

The new Claim 21 limitation of "said at least one egg including transfer factor that transfer cellular immunity to a mammal in vivo" is supported by Dopson's disclosure. See Dopson, U.S. Serial No. 09/954,961, p. 9, lines 4-9. Finally, Applicants disclose that transfer factors generally have molecular weights that range from approximately 3,000 – 6,000 Da. See Dopson, U.S. Serial No. 09/954,961 p. 2, lines 25-26. Thus, Applicant's disclosed range fully supports and encompasses the about 4,000 to about 5,000 Da range of new Claim 21.

b) <u>New Claim 22 is fully supported by the Dopson disclosure and corresponds to the proposed count</u>

In addition to the arguments discussed above under section a), new Claim 22 also introduces the limitation that the transfer factor is *specific for a systemic pathogen.* This limitation is supported by Dopson's disclosure of "still another feature of the present invention is the ability to produce a composition containing transfer factor

specific to virtually any selected antigen . . ." See Dopson, U.S. Serial No. 09/954,961, p. 8, lines 15-19. (*emphasis added*)

Moreover, the Hennen patent uses the terms antigen and pathogen interchangeably. See Hennen, col. 2, lines 12-14. Thus, the disclosure of "antigen" alone or in combination with the pathogenic agents disclosed in Dopson at p. 8, lines 15-19 supports the claim limitation to *pathogen*.

Finally, one of skill in the art would understand that injecting a non-mammalian animal with the particular antigens/pathogens listed on p. 8, lines 15-19 of Dopson would know that the pathogens were all examples of "systemic pathogens". Thus, Applicants have sufficient support for the limitation of "obtaining transfer factor specific for a systemic pathogen".

VIII. Requirements of 35 U.S.C. §135(b)

The Hennen Patent was issued on October 22, 2002 and was filed on September 21, 2000. Therefore, the Hennen Patent was never published and the 1-year date of 35 USC §135(b) should be calculated from October 22, 2002. The present Request for Interference and new Claims 21 and 22 from a Preliminary Amendment are being filed simultaneously herewith on October 21, 2003. Thus, Applicants are presenting claims that correspond substantially and/or identically to at least one of the claims of the Hennen Patent prior to 1 year from the date it was issued.

The Examiner is requested to declare an interference between Dopson and U.S. Patent No. 6,468,534 to Hennen, *et al.*

The Examiner is invited to telephone the undersigned should issues remain after consideration of the present Request to permit early resolution of same. Please charge any additional fees required by this Response to Deposit Account No. 50-2548.

Respectfully requested,

NELSON MULLINS RILEY & SCARBOROUGH

October 21, 2003
Date

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